NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BLAKE BAUER, Plaintiff, v. EAGLE PHARMACEUTICALS, INC. and SCOTT TARRIFF, Defendants.	Civil Action No.: 16-3091(JLL) **OPINION**

LINARES, District Judge.

This matter comes before the Court by way of a motion to dismiss an amended class action complaint, which motion was filed by Defendants Eagle Scott Pharmaceuticals, Inc. ("Eagle") and Scott Tarriff ("Tarriff"), collectively ("Defendants"). (ECF No. 19). Lead Plaintiffs Blake Bauer, Brent Kawamura and Guarang Patel (collectively, "Plaintiffs") have opposed this motion (ECF No. 24), and Defendants have replied to same (ECF No. 29). The Court decides this matter without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons stated below, Defendants' motion to dismiss is granted. The Court dismisses Plaintiffs' complaint without prejudice to the refiling of an amended pleading that cures the deficiencies identified herein.

I. Background[1]

A. Parties

[1] The facts as stated herein are taken as alleged in Plaintiff's Amended Complaint. (ECF No. 14, "Am. Compl."). For purposes of this motion to dismiss, these allegations are accepted by the Court as true. *See Phillips v. County of Allegheny,* 515 F.3d 224, 228 (3d Cir. 2008) ("The District Court, in deciding a motion [to dismiss under Rule] 12(b)(6), was required to accept as true all factual allegations in the complaint and draw all inferences from the facts alleged in the light most favorable to [the plaintiff].").

Defendant Eagle is a publicly-traded "specialty pharmaceutical company that focuses on developing and commercializing injectable products." (Am. Compl. ¶ 2). Eagle was founded in 2007 by Defendant Tarriff, the Company's Chief Executive Officer. (Id.).

Although Eagle is a pharmaceutical company, it does not focus on developing new drug therapies. (Id. ¶ 3). Rather, Eagle's business model focuses on "develop[ing] proprietary innovations that improve upon short-comings of existing FDA-approved, injectable drugs." (Id.). Under this model, Eagle seeks to utilize the FDA's 505(b)(2) New Drug Application ("NDA") regulatory pathway. (Id.). A pharmaceutical company seeking entry into the market under this regulatory pathway may "rely, *in part*, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application." (Id. ¶ 4). Thus, as compared to the regulatory regime applicable to novel drugs that may require extensive clinical testing, the 505(b)(2) pathway may offer companies a cheaper, faster route to approval. (Id. ¶ 3).

Plaintiffs, purchasers of Eagle common stock, bring this action on behalf of a putative class "of all persons who purchased Eagle common stock between May 12, 2015 and March 18, 2016, inclusive (the 'Class Period')." (Id. ¶ 1). Plaintiffs assert claims of securities violations against Defendants pertaining to an alleged "series of materially misleading statements and omissions concerning the Defendants' failed attempt to secure FDA approval of its ready-to-use ('RTU') liquid Bivalirudin product," which product Eagle unsuccessfully sought to introduce into the market through the 505(b)(2) pathway.

B. The Product

This action pertains to a particular product developed by Eagle, which product was originally known as "Kangio" ("the Product"). (Am. Compl. ¶ 10).[2] Consistent with Eagle's business model, the Product was not a novel drug. Rather, the drug was based off of a pre-approved drug called "Bivalirudin," which was developed by the Medicines Company and is marketed under the brand name "Angiomax." (Id. ¶ 6). In industry terms, Bivalirudin is the "reference drug" to Eagle's Product. Plaintiffs explain the differences between the Product and Bivalirudin as follows:

> Historically, Bivalirudin has been delivered to hospitals in powder form. Prior to being administered at the beginning of catheter laboratory ("cath lab") angioplasty procedures to prevent clotting, hospital pharmacists had to reconstitute the drug from powder form into liquid form, before the drug was further diluted into an IV bag. As described herein, Eagle developed [the Product] as a purportedly shelf-stable, liquid intravenous form of Angiomax that was ready-to-use. Eagle's development of a ready-to-use liquid form of Bivalirudin, if successful, meant that routine pharmacy compounding errors associated with the process of reconstituting Bivalirudin from powder form into liquid form could be eliminated, while the time and attention required to administer the drug could be reduced, both valuable improvements that caused excitement among analysists and investors.

(Id. ¶ 6).

Eagle and its investors were excited about the prospect of FDA approval of the Product. (Id. ¶ 8). On May 19, 2015, Eagle submitted a New Drug Application ("NDA") to the FDA, seeking approval through the 505(b)(2) regulatory pathway. (Id. ¶ 10). Plaintiffs allege that "[b]y June 30, 2015, the Company had announced that the NDA had been accepted as filed by the FDA and that the FDA action was due by March 19, 2016." (Id.). Plaintiffs further allege that in the

[2] According to Plaintiffs, "[o]n July 7, 2016, pursuant to ongoing patent litigation brought by Bivalirudin's original marketer against the Company, Eagle stipulated to abandon its trademark application for the name 'Kangio' and to remove the name from its still pending FDA NDA application and to cease using the name in any and all promotional marketing material." (Id. ¶ 5, n.1). Accordingly, hereinafter, the Court refers to the subject of the NDA as the "Product."

months following Plaintiffs' filing of the FDA, "Eagle assured investors that the Company was engaged in an ongoing, positive dialogue with the FDA." (Id. ¶ 11). Moreover, according to Plaintiffs, "in the weeks leading up to an anticipated FDA decision, Tarriff and Eagle created a materially misleading impression to investors that FDA approval of Kangio was highly likely, if not a fait accompli." (Id.).

However, on March 18, 2016, Eagle announced that it had received a Complete Response Letter from the FDA, which letter, in short, advised the Company that it would not approve Eagle's NDA relating to the Product in its present form. (Id. ¶¶ 13, 37). Critical Response Letters ("CRL"), because they relate to confidential drug developments, are generally not released to the public.[3] (Id. ¶ 38). However, Eagle's March 18, 2016 press release apprised investors of the CRL. (Id. ¶ 87). In pertinent part, Eagle's press release stated that: "In its letter to Eagle, the FDA requested further characterization of bivalirudin-related substances in the drug product." (Id.).

According to Plaintiffs, "[t]he share price of Eagle stock reacted sharply to this news[,] declining by $10.18 (or 18.9%) from the March 17, 2016 closing price of $53.68 to close at $43.50." (Id. ¶ 88). Citing to a research note from Piper Jaffray issued the same day that Eagle announced its receipt of the CRL, Plaintiffs state that the decline in share pricing is directly attributable "to the unexpected denial" of the Product NDA. (Id. ¶ 89).

C. Alleged Misrepresentations and Omissions

Generally, Plaintiffs allege that investors were misled into purchasing Eagle stock at inflated prices due to material misrepresentations and omissions made by Eagle and its CEO, Defendant Tarriff, specifically relating to the Product and its likelihood of receiving FDA

[3] As of the date that the briefs pertaining to the pending motion were filed, the CRL has not yet been publicly shared.

approval. These alleged misrepresentations can be classified, as in Plaintiffs' opposition brief, into two main categories: (1) "Defendants' representations that [the Product] was simply a liquid, 'ready to use' version of Angiomax," and; (2) Defendants' representations that FDA approval of [the Product's] NDA was imminent based on a continuing dialogue with the FDA." (ECF No. 24, "Pls.' Br." at 9-14).

As to the first category of statements, Plaintiffs argue that "[m]any of Defendants' Class Period descriptions of [the Product] contain references to Angiomax, with many specifically stating that [the Product] contained the same active ingredient, and that the only difference between the two drugs was that one was a liquid ([the Product]) and one was a powder (Angiomax) that needed to be reconstituted into a liquid before being administered." (Pls.' Br. at 9). Plaintiffs allege that these statements must be false given the fact that, as phrased by the press release, the FDA "requested further characterization of the *bivaliruden-related substances* in the drug product." (Id. at 9; Am. Compl. ¶ 87). Plaintiffs further maintain that Eagle "effectively conceded that [the Product] differed from Angiomax as previously disclosed" by stating that it is in discussions with the FDA about the design of a study that would "support approval of the product." (Pls.' Br. at 9-10; Am. Compl. ¶ 103).

As to the second category of statements, Plaintiffs do not dispute that Eagle and the FDA were, in fact, engaged in ongoing discussions leading up to the CRL. (Pls.' Br. at 13). However, Plaintiffs contend that Defendants' "statements about the dialogue were misleading in that they indicated that everyone was on track for an approval in March 2016, and that Eagle would be in a position to capitalize on a 'lucrative' market." (Id.). Specifically, Plaintiffs cite to the following statement made by Defendant Tarriff during a February 23, 2016 presentation: "We are in dialogue with the FDA, as you would expect coming down to the final weeks before approval. We have

every expectation that based on our file and the dialogue that's been ongoing that we'll get an approval. So, March 19, three and a half weeks, and we expect to launch." (Id.; Am. Compl. ¶ 76). Plaintiffs also allege that during a February 25, 2008 earnings call, Tarriff stated:

> [W]e currently expect to be the next entrant into this market [i.e., Bivalirudin] ahead of other generics . . . . So we feel good about our chances of capturing a meaningful share of that market. We have been interacting with FDA and we are preparing for launch, everything seems to be on track for a March 19 approval, and we anticipate shipping in late Q1 or early Q2. . . .

(Am. Compl. ¶ 11). In summary, according to Plaintiffs, Defendants' representations (1) that the Product was a RTU version of the name-brand product and (2) that FDA approval was imminent based on Defendants' dialogue with the FDA were both false and misleading.

D. Allegations

Against this backdrop, Plaintiffs filed this putative class action asserting securities violations under the Securities and Exchange Act of 1934 (the "Act"). Specifically, in Count I of the Amended Complaint, Plaintiffs assert a violation of Section 10(b) of the Act, and Rule 10b-5 promulgated thereunder. In Count II, Plaintiffs assert a derivative claim against Defendant Tarriff for violation of Section 20(a) of the Act. Defendants now move for a dismissal of this action for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). Defendants' motion has been fully briefed, and is now ripe for the Court's adjudication.

II. Legal Standard

Federal Rule of Civil Procedure 8(a) requires that a Complaint set forth "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P 8(a)(2). The plaintiff's short and plain statement of the claim must "'give the defendant fair notice of what the

. . . claim is and the grounds upon which it rests.'" *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 545 (2007) (quoting *Conley v. Gibson,* 355 U.S. 41, 47 (1957)). For a complaint to survive dismissal, it "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009) (quoting *Twombly,* 550 U.S. at 570).

In evaluating the sufficiency of a complaint, a court must "accept all well-pleaded factual allegations in the complaint as true and draw all reasonable inferences in favor of the non-moving party." *Phillips v. County of Allegheny,* 515 F.3d 224, 234 (3d Cir. 2008) (quotations omitted). "Factual allegations must be enough to raise a right to relief above the speculative level." *Twombly,* 550 U.S.at 545. Further, "[a] pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do. Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Iqbal,* 556 U.S. at 678 (quoting *Twombly,* 550 U.S. at 555, 557); *Evancho v. Fisher,* 423 F.3d 347, 350 (3d Cir. 2005) ("[A] Court need not credit either 'bald assertions' or 'legal conclusions' in a complaint when deciding a motion to dismiss."). To that end, a Court considering a motion to dismiss must take account of the elements necessary to plead the claims alleged in the complaint.

In this case, Plaintiffs seek relief under Sections 10(b) and 20(a) of the Securities Exchange Act. "Section 10(b) prohibits the 'use or employ, in connection with the purchase or sale of any security, . . . [of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe . . . ." *In re Ikon Office Solutions, Inc.*, 277 F.3d 658, 666 (2002) (quoting 15 U.S.C. § 78j(b)). Rule 10b-5, in turn, created a private right of action for investors harmed by materially false or misleading statements to enforce Section 10(b), and it "makes it unlawful for any person '[t]o make any untrue statement of a material fact

or to omit to state a material fact necessary to make the statements made in the light of the circumstances under which they were made, not misleading . . . in connection with the purchase or sale of any security.'" *Id.* (quoting 17 C.F.R. § 240.10b-5(b)).

> To establish liability under 10(b) and 10b-5, a plaintiff must show:
>
> (1) *a material misrepresentation (or omission);* (2) *scienter, i.e.,* a wrongful state of mind; (3) *a connection with the purchase or sale of a security;* (4) *reliance*, often referred to in cases involving public securities markets (fraud-on-the-market cases) as "transaction causation;" (5) *economic loss;* and (6) *"loss causation," i.e.,* a causal connection between the material misrepresentation and the loss.

Dura Pharm, Inc. v. Broudo, 544 U.S. 336 (2004) (internal citations omitted).

"Because this is a securities fraud case, . . . [the Court] does not merely ask, as [it] normally would under Rule 12(b)(6), 'whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Institutional Investors Group v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009) (quotations omitted). This is because the Private Securities Litigation Reform Act ("PSLRA"), applicable to this case, imposes a heightened pleading standard for claims arising under the Securities Exchange Act. *Id.* Specifically, under the PSLRA, a plaintiff must "state with particularity both the facts constituting the alleged violation, and the facts evidencing scienter, *i.e.,* the defendant's intention 'to deceive, manipulate, or defraud." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.,* 551 U.S. 308, 313 (2007) (quoting *Ernst & Ernst v. Hochfelder,* 425 U.S. 185, 194, and n. 12 (1976), and citing 15 U.S.C. § 78u–4(b)(1), (2)).

First, with regard to misleading statements and omissions of material fact, a plaintiff must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omissions is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u–4(b)(1). Further, "[t]o be actionable, [the] statement or omission must have been

misleading at the time it was made; liability cannot be imposed on the basis of subsequent events." *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1330 (3d Cir. 2002).

Second, as to the scienter requirement, with respect to each alleged wrongful misrepresentation or omission, a complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). Under the PSLRA, unlike the general rule for pleading fraud under FRCP 9(b), "any private securities complaint alleging that the defendant made a false or misleading statement must . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Avaya*, 564 F.3d at 253 (quoting, in full, *Tellabs*, 127 S. Ct. at 2504, 2508).

III. Discussion

Defendants argue that Plaintiffs' Amended Complaint should be dismissed because it fails to meet the heightened pleading standards of a securities fraud claim. Among other arguments, Defendants maintain that Plaintiffs have not sufficiently pled the first element of a 10(b) claim—namely, a material misrepresentation or omission.[4]

As noted above, to survive a motion to dismiss a claim brought under the PSLRA, a plaintiff must "specify each allegedly misleading statement, why the statement was misleading, and if an allegation is made on information and belief, all facts supporting that belief with particularity." *Winer Family Tr. v. Queen*, 503 F.3d 319, 326 (3d Cir. 2007). Here, Plaintiffs' opposition brief categorizes the challenged statements into two categories: (1) "Defendants'

[4] Defendants also maintain that Plaintiffs failed to adequately plead scienter and loss causation—respectively, the second and sixth elements of their Section 10(b) fraud claim. However, because the Court finds that Plaintiffs have not pled the first element of their claims, the Court need not address the remaining elements. That said, and because the Court will permit Plaintiffs an opportunity to file an amended complaint, the Court only notes that Plaintiffs should be cognizant of the heightened pleading requirements with respect to scienter under the PSLRA.

representations that [the Product] was simply a liquid, 'ready to use' version of Angiomax" and; (2) "Defendants' representations that FDA approval of [the Product's] NDA was imminent based on a continuing dialogue with the FDA." (Pls.' Br. at 9, 13). In a similar vein, Plaintiffs have alleged a securities violation based upon Defendants' failure to disclose that there were significant differences between the Product and the reference drug and based upon Defendants' failure to disclose that additional human studies would likely be required to achieve FDA approval. (Am. Compl. ¶¶ 62, 64).

According to Defendants, Plaintiffs have not pled any particularized facts tending to support their allegations that the challenged statements were false or otherwise misrepresentations, or that any omissions rendered any statements false or misleading. Specifically, Defendants state that the statements or omissions upon which Plaintiffs base their claims are inactionable in that they are either demonstrably true, are prohibited by the PSLRA's safe harbor provision, are/or are mere puffery. (ECF No. 19-1, "Defs.' Mov. Br. at 14-23). The Court considers each of these arguments, as well as Plaintiffs' responses thereto, in turn.

A. Whether Plaintiffs have sufficiently alleged that the Challenged Statements were False

Defendants argue that many of the alleged misrepresentations or omissions are inactionable because they are accurate statements of fact. (Defs.' Mov. Br. at 22-23).[5] In other words, Defendants maintain that "the '[Amended] Comlaint fails to satisfy the 'PSLRA's first pleading requirement,' which is to specify each allegedly misleading statement and 'the reason or reasons

[5] Defendants contend that Plaintiffs have failed to state why the following five categories of statements are untrue: the characteristics of the Product; the Product's NDA and PDUFA date; discussions with the FDA; the Company's business model; and the Product's launch, are all true statements that cannot form the basis of Plaintiff's claim for misrepresentation or omission. (Id.). Given that Plaintiffs group their challenged statements into two categories—(1) relating to the likelihood of FDA approval and (2) the chemical make-up of the Product—to the extent possible, the Court's discussion groups

why the statement is misleading.'" (Id. at 22, quoting *Avaya*, 564 F.3d at 259, 267 (internal quotations omitted)). Of the two main categories of statements as organized by Plaintiff—that is, statements relating to the Product's make-up and statements regarding the likelihood of FDA approval—it is allegations relating to the chemical make-up of the Product that underlie the majority of the challenged statements. In other words, Plaintiffs' allegations that Defendants misled investors with representations as to the likelihood of FDA approval are, to a large extent, premised upon their allegations that Defendants were somehow aware, via their discussions with the FDA and otherwise, that the Product was not merely a RTU version of the branded drug and would require human clinical trials. Accordingly, the Court will first address Defendants' argument that Plaintiffs have not sufficiently pled that Defendants' statements regarding the nature of the Product were false.

Plaintiffs offer two factual allegations that they argue show that Defendants' statements relating to the composition of the Product and the Product's status as a "ready to use" form of Angiomax were misrepresentations. Principally, Plaintiffs rely upon the fact that the CRL, as summarized by the Company in its press release, "requested further characterization of the bivalirudin-related substances in the drug product." (Pls.' Br. at 9). Second, Plaintiffs rely upon the fact that Eagle has confirmed that it is currently in discussions with the FDA to develop a human clinical trial. (Id.). According to Plaintiffs, if the Product was "truly just a liquid form of Angiomax," then the now-contemplated human studies would not be necessary. (Id. at 9-10).

For their part, Defendants contend that Plaintiffs have not alleged any facts that tend to contradict the Company's representations as to the nature of the Product. (Def.'s Mov. Br. at 23). Specifically, Defendants stated that "[t]he fact that the FDA did not approve the NDA does not, for instance, render Defendants' descriptions of RTU Bivalirudin false." (Id.). Similarly,

Defendants argue that the Amended Complaint does not contain any particularized facts suggesting that Defendants concealed differences between RTU Bivalirudin and Anigomax. (Id. at 24-25). First, Defendants note that while the Amended Complaint alleges "significant differences" between the Product and the reference drug, the Complaint does not state what those alleged differences are. (Id.). Second, Defendants note that no reasonable investor could have been misled into thinking that the Product was identical to Angiomax, since "Eagle's entire business model is premised on *making changes* to the branded reference drug and utilizing the 505(b)(2) pathway." (Id. at 25). Additionally, addressing Plaintiffs' argument that Defendants' post-class period statements that they are engaged in discussions with the FDA regarding conducting human clinical trials, Defendants note that "[t]hese discussions do not show that *during the Class Period* Defendants were aware of the need for human trials." (Defs.' Mov. Br. at 30). And, as Defendants point out, Plaintiffs have not pled any factual allegations tending to show that, during the Class Period and at the time that any of the challenged statements were made, Defendants had any reason to believe that human clinical trials would be required.

The Court agrees with Defendants that Plaintiffs have not sufficiently pled particularized facts demonstrating how any representations regarding the composition of the Product were false. The sum and substance of Plaintiffs' argument relating to the Product's composition is as follows: In light of the CRL requesting further information on the "bivalirudin-related substances," and in light of the fact that Eagle is now in discussions with the FDA regarding human trials, it must be the case that Defendants' statements that the Product was a RTU-version of Angiomax were false. (See Pls.' Br. at 10). Yet, Plaintiffs have failed to explain how this is so. While the Court acknowledges that Plaintiffs may lack information due to the confidentiality of the CRL, this fact does not give Plaintiffs the authority to speculate. That is, speculation and conjecture will not

support a claim under the PSLRA's heightened pleading standard. *See, e.g., California Public Employees' Retirement System v. Chubb Corp.*, 394 F.3d 126, 155 (3d Cir. 2004) ("Generic and conclusory allegations based upon rumor and conjecture are undisputedly insufficient to satisfy the heightened pleading standard of 15 U.S.C. § 78u-4(b)(1).").

In summary, the Court finds that Plaintiffs have failed to plead with sufficient particularity any facts tending to support their theory that Defendants' statements relating to the characteristics of the Product were false. Accordingly, Plaintiff has not met the heightened pleading standard of the PSLRA with respect to these particular challenged statements. Thus, to the extent Plaintiffs' claims are premised upon statements regarding the composition of the Product, those claims are not actionable.

B. The PSLRA's Safe Harbor Provision

As to the second category of challenged statements relating to the likelihood of FDA approval, Defendants maintain that these statements are not actionable as they are protected under the PSLRA's "safe harbor" provision. (Defs.' Mov. Br. at 15). The PSLRA contains a "safe harbor" provision, which, in pertinent part, protects oral or written forward-looking statements from Rule 10b-5 liability. 15 U.S.C.A. § 78u–5. Specifically, § 78u-5(c)(1)(A) provides that:

> [A] person . . . shall not be liable with respect to any forward-looking statement, whether written or oral, if and to the extent that (A) the forward-looking statement is (i) identified as a forward-looking statement, and is accompanied by meaningful cautionary language statements identifying important factors that could cause actual results to differ materially from those in the forward looking statement; or (ii) immaterial; or (B) the plaintiff fails to prove that the forward-looking statement . . . was made with actual knowledge [on the part of the individual making the statement] that the statement was false or misleading.

Id. The safe harbor provision defines a "forward-looking statement" broadly, to include:

> (A) a statement containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items;

> (B) a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer;
> (C) a statement of future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management or in the results of operations included pursuant to the rules and regulations of the [SEC];
> (D) any statement of the assumptions underlying or relating to any statement described in subparagraph (A), (B), or (C).

15 U.S.C.A. § 78u–5(i)(1).

In order for a forward-looking statement to be protected by the safe harbor provision, it must be tempered by cautionary language that is "directly related to the alleged misrepresentations," but such cautionary language does not have to "actually accompany the alleged misrepresentation." *GSC Partners CDO Fund v. Washington,* 368 F.3d 228, 243 (3d Cir.2004) (quoting *EP Medsystems, Inc. v. EchoCath, Inc.,* 235 F.3d 865, 874 (3d Cir.2000)); *see also Semerenko v. Cendant Corp.,* 223 F.3d 165, 182 (3d Cir.2000) (quoting *In re Donald J. Trump Casino Sec.* Litig.-Taj Mahal Litig., 7 F.3d 357, 369 (3d Cir.1993)). "Cautionary language must be extensive and specific." *Avaya*, 564 F.3d at 256 (quoting *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 243 n.3 (3d Cir. 2004). In *In re Trump*, the Third Circuit explained:

> [A] vague or blanket (boilerplate) disclaimer which merely warns the reader that the investment has risks will ordinarily be inadequate to prevent misinformation. To suffice, the cautionary statements must be substantive and tailored to the specific future projections, estimates or opinions in the prospectus which the plaintiffs challenge.

In re Trump, 7 F.3d at 371–72. In *Kline v. First Western Gov't Sec., Inc.*, 24 F.3d 480, 489 (3d Cir.1994), the Third Circuit clarified that "*Trump* requires that the language bespeaking caution relate directly to that by which plaintiffs claim to have been misled."

Finally, even if a defendant can show that challenged statements were forward-looking and accompanied by cautionary language, the safe harbor clause will not apply if the statement was made with actual knowledge that the statement was false or misleading. 15 U.S.C. § 78u–5(c)(1)(B)(i); *In re Advanta Corp.*, 180 F.3d at 535.

i. Whether Challenged Statements were "Forward-Looking"

Here, Defendants argue that the vast majority of the challenged statements are protected under the safe harbor provision. (Defs.' Mov. Br. at 15). Generally, these statements relate to the Company's belief that the NDA would be approved. Specifically, Defendants state that the following statements, as taken from the Amended Complaint, are forward-looking:

- "We will file the NDA for RTU bivalirudin in the very near future and would *expect its acceptance for filing by the end of July* and our PDUFA date should be 10 months after filing." (Am. Compl. ¶ 59) (emphasis in Defendnats' brief).
- "[W]e're going to do everything we can, and we think we have a good position to get us through and on to the market as soon as we possibly can." (Am. Compl. ¶ 61).
- "We look forward to the FDA's decision on this NDA in March 2016 and, *if approved, intend to launch* our RTU bivalirudin product the following day. . . ." (Id. ¶ 63) (emphasis in Defendants' brief).
- "We *expect to launch* RTU bivalirudin in March. . . ." (Id. ¶ 65) (emphasis in Defendants' brief)
- "So we *believe* we will gain very strong market share with this product. It should be sticky. . . ." (Id. ¶ 66) (emphasis in Defendants' brief).
- "[W]e continue to *expect* an FDA decision in March 2016." (Id. ¶ 68) (emphasis in Defendants' brief).
- "We have every *expectation* that based on our file and the dialogue that's been ongoing that we'll get an approval." (Id. ¶ 76) (emphasis in Defendants' brief).
- "We currently *expect* to be the next entrant into this market ahead of other generics. . . . So we feel good about our chances of capturing a meaningful share of that market." (Id. ¶ 83).

Defendants maintain that courts have routinely found similar statements to be forward-looking under the PSLRA. (Defs.' Mov. Br. at 17).

In opposition, Plaintiffs argue that these statements are not forward-looking. (Pls.' Br. at 21). Specifically, Plaintiffs state that "with respect to the expectation that the NDA would be approved and the product would launch in March of 2016, the statements Defendants argue are forward looking are actually based on past interactions and 'ongoing' and 'continuing' then-

present discussions with the FDA." (Id. at 22) (citing to Am. Compl. ¶¶ 63, 76, 83).[6] Moreover, Plaintiffs contend that

> Defendants' statements regarding their expectation that [the Product] would be the next entrant into a limited market and would therefore capture "a meaningful share of the market" (¶ 83) were similarly a representation of present conditions, namely that: (i) FDA approval was imminent; (ii) competitors were locked in protracted patent litigation which would prevent them from entering the market before Eagle (¶ 49); and (iii) [the Product's] formulation was such that it was eligible for fast-track approval.

(Id. at 22-23).

The Court agrees with Defendants that the above-listed challenged statements, as taken directly from Defendants' moving brief, are forward-looking statements. That is, statements relating to anticipated FDA approval of the NDA are "statement[s] of the plans and objectives of management for future operations, including plans or objectives relating to the products." 15 U.S.C.A. § 78u–5(i)(1)(B). Just as in *Avaya*, where the Third Circuit affirmed the district court's finding that "the 'on track' and 'position us' portions of the [challenged statements], when read in context, cannot meaningfully be distinguished from the future projection of which they are a part," *Avaya*, 564 F.3d at 255, this Court finds that the above statements anticipating FDA approval are not transformed into mixed present/future statements by virtue of references to the "ongoing" and "continuing" discussions with the FDA. (See Pl.'s Br. at 22). This is particularly the case where Plaintiffs concede that Defendants and the FDA were, in fact, engaged in discussions.

ii. Whether Challenged Statements were Accompanied by Cautionary Language

[6] Plaintiffs also state that "statements concerning the chemical composition of [the Product], and its eligibility for a streamlined FDA approval process because it is a reconstituted version of an already-approved drug, are clearly not forward-looking." (Pls.' Op. Br. at 21-22). However, the Court does not construe any of the statements that Defendants have identified as forward-looking to be related the composition of the Product. Accordingly, the Court sees this argument as inapposite.

Having found that the statements relating to the likelihood of FDA approval were forward-looking, the Court must determine whether they were properly accompanied by cautionary language.

According to Defendants, the above statements were countered by cautionary language in the Company's Form 10-Q and Form 10-K. (Defs.' Mov. Br. at 17-18). Eagle's Form 10-Q for the quarterly period ending March 31, 2015 states that the Form contains forward-looking "statements about: the success, cost and timing of our product development activities and clinical trials; [and] our ability to obtain . . . regulatory approval of our product candidates. . . ." (Defs.' Mov. Br. at 18, Exh. 20). Specifically, the Form 10-Q contains the following statements:

- "We cannot provide assurance that we will be able to obtain approval for any of our product candidates from the FDA or any foreign regulatory authority or that we will obtain such approval in a timely manner." (Exh. 20 at 25)
- "The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the branded reference drug, which could be time consuming and could substantially delay our achievement of regulatory approvals for such product candidates." (Id. at 25-26).

Moreover, the Company's Form 10-K contained the following statements:

- "If the FDA does not allow us to pursue the 505(b)(2) regulatory pathway for our product candidates as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates would likely substantially increase . . . [and] could result in new competitive products reaching the market faster than our product candidates, which could materially adversely impact our competitive position and prospects. Even if we were allowed to pursue the 505(b)(2) regulatory pathway for a product candidate, we cannot assure you that we will receive the requisite or timely approval for commercialization of such product candidate."
- "It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval in the United States or other jurisdictions."
- "Our product candidates could fail to receive regulatory approval . . . [because] we may be unable to demonstrate to the satisfaction of the FDA . . . that a product candidate is safe and effective or comparable to its branded reference products for its proposed indication. . . ."

(Defs.' Mov. Br. at 18-19, Exh. 19).

Defendants argue that the above cautionary statements are extensive, specific, and narrowly-tailored to address the challenged statements. (Defs.' Mov. Br. at 19). That is, "Eagle's cautionary language warned investors about the very risks of which Plaintiffs now complain." (Id.).

Plaintiffs challenge these statements as appropriately cautionary. (Pls.' Op. Br. at 24-25). According to Plaintiffs, these statements are merely vague, boilerplate language that fails to "identif[y] the specific facts posing risks to the approval of RTU Bivalirudin, namely that the Bivalirudin-related substances in [the Product] were not the same as in Angiomax, such that [the Product] was ineligible for fast-track approval." (Id. at 24).

The Court agrees with Defendants that the above cautionary statements, as identified in the Form 10-Q and Form 10-K, were sufficiently "extensive and specific." *Avaya*, 564 F.3d at 256. These statements, in no uncertain terms, warn investors that FDA approval through the 505(b)(2) regulatory pathway is not guaranteed, that the FDA may require additional, time consuming testing, and finally, that the FDA may find that Defendants' products are not, in fact, comparable to the branded drug. Each of these warnings are sufficiently tailored to Defendants' statements relating to the risks that came to fruition and form the basis of Plaintiffs' complaint. Moreover, Plaintiffs' argument that the warnings are insufficient because they fail to warn investors that "the Bivalirudin-related substances in [the Product] were not the same as in Angiomax" is simply an attempt to bootstrap the alleged misrepresentation/omission into the required warnings. Thus, were the Court to credit this argument, the Court would necessarily be accepting Plaintiffs' argument that the failure to notify of alleged differences between the Product and reference drug was, in fact, an actionable omission. For the reasons discussed above, however, the Court finds

that Plaintiffs have not sufficiently pled allegations to substantiate their claims that Defendants misrepresented the nature of the Product.

In summary, the Court finds that any allegations as to the likelihood of FDA approval of the Product's NDA and potential launch date of the product were forward-looking and accompanied by cautionary language.

iii. Whether Defendants had "Actual Knowledge" of the Falsity of their Statements

Although the Court has found that many of the suspect statements were forward-looking and accompanied by appropriate cautionary language, the safe harbor provision will not apply if statements were made with actual knowledge of their falsity. 15 U.S.C. § 78u–5(c)(1)(B)(i); *In re Advanta Corp.*, 180 F.3d at 535. Accordingly, the question at this juncture is whether Plaintiffs have sufficiently pled that Defendants had actual knowledge that their statements respecting the likelihood of FDA approval were false or misleading.

Here, the Court finds that Plaintiff has not sufficiently pled that the Defendants had actual knowledge of the falsity of their statements. Plaintiff argues that "[t]he FDA's fundamental disagreement with Eagle's characterization of [the Product's] composition, following more than nine years of development and an ongoing dialogue with the FDA that continued into the weeks before the FDA's CRL, 'support[s] an inference of scienter.'" (Pls.' Op. Br. at 27). In other words, Plaintiff states that "the fact that the Company was admittedly engaged in an ongoing dialogue with the FDA, which ultimately expressed concerns about [the Product], gives rise to the inference that the FDA either directly asked questions or expressed concerns that required follow-up prior to the release of the CRL." (Id. at 27-28).

In response, Defendants contend that the Complaint fails to allege what, if anything the FDA allegedly said to Defendants during their Class Period discussions which would lead Defendants to believe that FDA approval would not be forthcoming. (Defs.' Mov. Br. at 29). Rather, from Defendants' perspective, Plaintiffs' argument "amounts to pure speculation—*i.e.*, that Defendants 'must have known' about the FDA's concerns simply because they were engaged in ongoing dialogue." (Id.).

Plaintiffs also encourage the Court to impute scienter to Defendants by virtue of the "inference that key officers have knowledge of the 'core operations' of a company." (Id. at 28). According to Plaintiff, the Company's small size of less than 45 employees and the significance of the Product to the Company's bottom-line further support an inference of scienter. (Id. at 28-29). That is, given this information, "Tarriff cannot credibly disavow knowledge of the [Product's] development process and its likelihood of success." (Id. at 29).

However, the alleged misrepresentations with respect to the Product's launch date are largely based upon allegations that Defendants' representations that the Product was a RTU version of the referenced drug were false. Yet, as discussed above, the Court finds that Plaintiff has failed to sufficiently plead that these allegations were, in fact, false. Because the Court finds that Plaintiff has not pled falsity as to these statements, there is no basis from which to conclude that the Company's on-going discussions with the FDA, coupled with the core operations doctrine, supports an inference that Defendants knew that the Product's NDA would not be approved.

Plaintiffs also attempt to bolster the inference of scienter by demonstrating that Defendants had a motive and opportunity to mislead investors. (Pls.' Br. at 32-35). However, because a plaintiff cannot "establish scienter through proof of motive or opportunity alone," and because the

Court has already found that Plaintiffs have not sufficiently pled scienter, the Court need not address this argument.

In summary, the Court finds that Plaintiffs' allegations that Defendants' statements relating to the likelihood of FDA approval are protected by the safe harbor provision. Therefore, these statements cannot form the basis of Plaintiffs' claims.

C. Puffery

In addition to arguing that many statements are protected by the safe harbor clause, Defendants contend that "[m]any of the challenged statements are also inactionable statements of opinion, puffery, and corporate optimism." (Defs.' Mov. Br. at 20).

While material misrepresentations may be actionable, such "representations must be contrasted with statements of subjective analysis or extrapolations, such as opinions, motives and intentions, or general statements of optimism." *EP MedSystems, Inc. v. EchoCath, Inc.*, 235 F.3d 865, 872 (3d Cir. 2000). As the Third Circuit has stated, these "statements 'constitute no more than 'puffery' and are understood by reasonable investors as such.'" *In re Aetna, Inc. Securities Litig.*, 617 F.3d 272, 283 (3d Cir. 2010) (quoting *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 538 (3d Cir. 1999), abrogated on other grounds as recognized in *Avaya, Inc.*, 564 F.3d at 276).

Here, Defendants contend that the following statements fall into the category of inactionable puffery:

- "Bivalirudin is a *unique product.*" (Compl. ¶ 59).
- "[W]e have a product that *we consider far superior* to the other generics on the market." (Id. ¶ 78).
- "[W]e think we have a good position to get us through and on to the market as soon as we possibly can." (¶ 61).
- "[E]verything seems to be on track for a March 19 approval . . . ." (Id. ¶ 83).
- "We expect our RTU liquid formulation will be *well received* due to its multiple differentiating features." (Id. ¶ 63).
- "*I think* on bivalirudin, we should do *very well.*" (Id. ¶ 66).

- "So *we believe* we will gain *very strong* market share with this product. It *should be sticky*." (Id.).

According to Defendants, these are the type of vague statements of puffery or corporate optimism that cannot be said to mislead reasonable investors. (Defs.' Mov. Br. at 20-22).

Plaintiffs contend that "the challenged statements are definitive, verifiable statements regarding the essence of [the Product] and the likelihood that RTU Bivalirudin would gain FDA approval without onerous and costly human trials, and there is no question that such statements were material to investors." (Pls.' Br. at 15). However, as to the first category of statements (relating to the chemical composition of the Product), and as Plaintiffs noted in their opposition brief, Defendants are not arguing that any statements pertaining to the chemical makeup of the Product were puffery. (Pls.' Br. at 15). Moreover, as to the second category of statements (i.e., the likelihood of FDA approval), the Court has already determined that these claims are protected under the safe harbor provision.

The remaining statements enumerated above that do not fall into the category relating to FDA approval, for example, the Company's statements that the Product is "unique," "far superior" to other generic drugs, should do "very well" and will be "well received" are not the kind of statements that a "reasonable investor making an investment decision" would have relied upon. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997). Accordingly, the Court agrees with Defendants that, to the extent Plaintiffs are relying upon such statements in support of their Section 10(b) claim, such statements are not actionable.

In summary, the Court finds that Plaintiffs have failed to plead the first element of their claim of a violation of Section 10(b) of the Securities and Exchange Act. Because Plaintiffs fail to sufficiently plead this primary violation, Plaintiffs' claim for individual liability as against Defendant Tarriff pursuant to Section 20(a) also fails. *See In re Merck & Co., Inc. Sec. Litig.*, 432

F.3d 261, 275 (3d Cir. 2005) ("[C]ontrolling-person liability is 'premised on an independent violation of the federal securities laws.'") (quoting *In re Rockefeller Ctr. Props, Inc. Sec. Litig.*, 311 F.3d 198, 211 (3d Cir. 2002)).

IV. Conclusion

For the reasons stated herein, Plaintiffs' Amended Complaint is hereby dismissed without prejudice. An appropriate Order accompanies this Opinion.

IT IS SO ORDERED.

DATED: May 19, 2017

JOSE L. LINARES, U.S.D.J.